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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/551,665

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1114-10 PCT/US

2899

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EXAMINER

BADR, HAMID R

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/551,665	Applicant(s) SKOP ET AL.	
	Examiner HAMID R. BADR	Art Unit 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-40 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>3/16/2006, 9/18/2006</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 3-4, 9-10, 17-18, 26-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

3. Level of skill in the art: The specification does not include any guidance on how to make a confection to contain the number of live organisms as presently claimed.

4. The presence of Examples: There are no examples of formulations to demonstrate products containing live organisms. On the other hand since the probiotic bacteria are sensitive to fluctuations in water activity (A_w) in the product, no guidance has been given in the specification so that an artisan could make and use the invention.

5. Level of Unpredictability: Since the probiotic bacteria in a product need to be alive to be nutritionally effective, there is no evidence in the specification that the probiotic bacteria, as presently claimed, will be predicted to be alive for the shelf life of the product.

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6. For these reasons undue experimentation is required and the specification does not enable a person skilled in the art to practice the invention commensurate in scope with these claims.

7. Claim 35-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

8. Level of skill in the art: The specification does not include evidence to demonstrate the effectiveness of the immune function enhancing methods presently claimed.

9. The presence of Examples: The examples provided by the applicant have a limited showing with respect to enhancing the immune function of a host.

10. Level of Unpredictability: Since the suppression or malfunction of immune system could be due to various immunological factors, the methods as presently claimed will be highly unpredictable in enhancing the immune functions of hosts.

11. For these reasons, the specification does not enable a person skilled in the art to practice the invention commensurate in scope with these claims.

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12. Claims 2, 8, 16, 25, 39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claim limitation "contains no dairy" is not described in the specification in such a way as to convey to one skilled in the relevant art, that the inventors, at the time the application was filed, had possession of the claimed invention.

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 1-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite for "of an effective amount of". The term "effective" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear over what standard this is to be "effective", and also what properties are going to change due to the effectiveness of what is claimed. It is unclear what the applicants regard as the invention.

15. Claim 4 is indefinite for failing to further limit the claim on which it depends. While claim 3 sets the upper limit of the amount to be 2×10^5 organisms, claim 4 limits the

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number of organisms to at least 2×10^5 which will include any number above the upper limit of claim 4.

16. Claims 3-4, 9-10, 17-18, 26-27 are indefinite for “per confection”. Since “confection” refers to the product type and not the unit or dose, it is unclear what is meant by “per confection”. It is suggested to use phrases such as [per piece] or [per gram] or [per serving].

17. Claims 35-38 are indefinite for “an effective amount of a confection”. The specification does not disclose or describe what is meant by this phrase. It is not clear what the applicants regard as the invention.

Claims 35-38 are indefinite for “enhancing”. The term “enhancing” is a relative term which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear over what standard this is to be “enhancing”, and also what properties are “enhanced” (i.e. faster recovery time, increased immune titre, etc.).

18.

Claim Rejections - 35 USC § 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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20. Claims 1-34 rejected under 35 U.S.C. 103(a) as being unpatentable over Chau et al. (US 6,517,886; hereinafter R1) in view of Bell et al. (WO 02/00033; hereinafter R2).

21. R1 discloses an uncooked, unspun confectionary composition which provides a soft yet unsticky chew texture. (Abstract).

22. R1 discloses shear mixing without cooking or spinning a bioaffecting agent into the mixture. The bioaffecting agent could be a food, a nutritional component, dietary soluble or insoluble fiber, vitamin or mineral for affecting a biological and/or chemical response in the body. (Col. 7, lines 13-23)

23. Given that R1 discloses a composition which is uncooked, it can serve as a delivery system for heat sensitive materials including probiotic organisms.

24. While R1 clearly discloses the incorporation, into the delivery matrix, of functional components affecting biological and/or chemical response, R1 is silent regarding the inclusion of probiotics, prebiotics, co-enzyme Q10, inulin, and honey into the matrix.

25. R2 discloses a confectionery product which can include one or more active ingredients. (Abstract).

26. R2 discloses that the confectionery material may include nougat, fondant, caramel, chews, chewing gum etc. (page 3, lines 4-6).

27. R2 discloses that the active ingredient may be any vitamin, enzyme, mineral salt, antioxidants, probiotics, prebiotics, functional fiber, carnitine (page 4, lines 1-4). R2 discloses that the antioxidant can be co-enzyme Q10, or honey. (page 4, lines 34-36).

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The prebiotic may contain fructose, or inulin (page 5, lines 1-2) and probiotic bacteria may be *Lactobacilli*, *Bifidobacteria*, *Lactococci*, *Streptococci*, etc. (page 5, lines 5-7).

28. While R2 does not disclose the probiotic species, the species as presently claimed are all known in the art. The enzyme component as disclosed by R2 can be any enzyme including lactase and papain as presently claimed. Lactase and papain are being specifically included to provide lactase to lactose intolerant individuals and papain, as digestive aid, to assist in the hydrolysis of proteins.

29. Given that R2 discloses the inclusion of probiotic organisms, the number of colony forming units (CFU) per piece as presently claimed can be figured out by an artisan.

30. Given that R1 discloses an uncooked delivery matrix for nutritional compounds, and given that R2 teaches incorporating probiotics, prebiotics, Co-enzyme Q10, inulin, honey etc. it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to make a delivery matrix as taught by R1 and incorporate nutritional supplements as disclosed by R2. One would do so to have an uncooked delivery system which can incorporate and protect the heat sensitive materials including the probiotic bacteria. Absent any evidence to contrary and based on the combined teachings of the cited references, there would be a reasonable expectation of success in making a chewable confection as presently claimed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAMID R. BADR whose telephone number is (571)270-3455. The examiner can normally be reached on M-F, 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hamid R Badr
Examiner
Art Unit 1794

/KEITH D. HENDRICKS/
Supervisory Patent Examiner, Art Unit 1794